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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,015	11/16/2001	David H. Stewart	5470.296DV	4464

20792 7590 06/03/2003

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EXAMINER
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CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
**09/991,015**

Applicant(s)  
**Stewart**

Examiner  
**Arun Chakrabarti**

Art Unit  
**1634**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Apr 21, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 113-117 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 113-117 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☒ Other: Detailed Action

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## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 113-117 are rejected under 35 U.S.C. 102 (b) as being anticipated by Hadler et al. (Proceedings of the National Academy of Sciences (USA), (1971), Vol. 68, pages 1421-1424).

Hadler et al teach a labeled member of a binding pair (Abstract), comprising:

- a) a binder selected from proteins or immunoglobulins (Abstract and Introduction Section, Methods Section, Materials section, and Discussion Section); and
- b) an exogenous peptide label containing one or more modified amino acids capable of being oxidized in an oxidation-reduction reaction at potentials below those of naturally occurring amino acids (Abstract and Introduction Section, Methods Section, Materials section, and Discussion Section).

Use of the labeled binding pair for mediated catalytic electrochemistry has not been given any patentable weight because a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably

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distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art.

Hadler et al teach a labeled member, wherein the binder is an antibody (Abstract and Introduction Section, Methods Section, Materials section, and Discussion Section).

Hadler et al teach a labeled member, wherein there are at least two modified amino acids in the peptide label ( Discussion Section, page 1424, Column 2, first three paragraphs).

Hadler et al teach a labeled member, wherein the modified amino acids in the peptide label are selected from derivatives of tyrosine, 3-aminotyrosine (Abstract and Introduction Section, Methods Section, Materials section, and Discussion Section).

### ***Response to Arguments***

3. Applicant's arguments filed on April 21, 2003 have been fully considered but they are not persuasive.

Applicant argues (Page 1, second paragraph to page 2, line 7) that 102 (b) rejection based on Hadler et al should be withdrawn because Hadler et al does not teach or suggest the exogenous peptide label of the claimed invention. This argument is not persuasive. Hadler et al clearly teaches and suggests at least two modified amino acids in the peptide label ( Discussion Section, page 1424, Column 2, first three paragraphs). The label used by Hadler is an affinity label made of m-nitrobenzene diazonium fluoroborate, which leads to selective modification of the

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tyrosine at position 34 in the light chain of the gamma A myeloma protein 315 from the mouse (Abstract and Results Section). The azotyrosine bond was reduced with dithionite by Hadler to form 3-aminotyrosine, which is known to an ordinary practitioner skilled in the art as being capable of being oxidized in an oxidation-reduction reaction at potentials below those of naturally occurring amino acids. Therefore, the label of Hadler is clearly exogenous and meets all the requirements of the claim, especially the presence of "comprising" language of the claim allows additional step(s) or material(s) used by Hadler. It is not a requirement of the claim that the peptide comprising the label must be exogenous. Applicant refers to specification at page 28, "Exogenous labels are moieties that are added to binding members or targets by synthetic, artificial, natural or other means. The role of exogenous labels is to impart electrochemical activity on a molecule that would otherwise be electrochemically inactive or to increase the electrochemical activity of an already active molecule". It is not disclosed anywhere in the specification that the label must bind to an exogenous peptide. Moreover, the rejected claims does not recite that the exogenous peptide bound to the label of section (b) of independent claim 113 has to be different than the binder selected from any protein or protein fragments of section (a).

Applicant also requests (second paragraph of page 2) to particularly note claim 117, which allegedly exemplifies exogenous peptide labels of the claimed invention. This request has been considered but is not persuasive. Hadler et al clearly teaches all the elements of claim 117, which is a labeled member, wherein the modified amino acids in the peptide label are selected from

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derivatives of tyrosine, 3-aminotyrosine (Abstract and Introduction Section, Methods Section, Materials section, and Discussion Section).

In view of the response to arguments, 102 (b) rejection of the last office action is hereby properly maintained.

***Conclusion***

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CAR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. Any inquiry of a general nature or

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relating to the status of this application should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located In Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published In the Official Gazette, 1096 OG 30 (November 15, 1989).

Arun Chakrabarti

Patent Examiner

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May 20, 2003

  
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